

AWARD NUMBER: W81XWH-14-1-0005

TITLE: Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

PRINCIPAL INVESTIGATOR: Mark Ilgen, Ph.D.

CONTRACTING ORGANIZATION: Regents of the University of Michigan
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14. ABSTRACT Reducing suicide risk among active duty soldiers and Veterans is a national priority. Because substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD Treatment. The proposed research study addresses this gap by testing the efficacy of a targeted intervention designed to reduce suicide risk in Veterans treated for SUDs. The primary objective of this study is to evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) condition on subsequent suicidal thoughts and behaviors in Veterans with SUDs. During this research period, project staff have been refining study materials and measures, hiring key project staff, submitting applications to various regulatory boards for approval, receiving					
15. SUBJECT TERMS Suicide, Veterans, Substance Use Disorders					
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1. INTRODUCTION

The evaluation of strategies to reduce suicide among former members of the US armed forces is of high public health significance. Previous research has found that substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors. Because of this, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD treatment. Testing an intervention for use with suicidal Veterans seen in intensive outpatient SUD treatment programs within various Veteran Affairs Medical Centers (VAMCs) has the potential to significantly improve functioning and well-being, and decrease the substantial loss of life in Veterans with SUDs due to suicide. The overall purpose of this project is to adapt and evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) intervention on subsequent suicidal thoughts and behaviors in Veterans with SUDs. The study has two primary components: (a) refining the intervention content for use in Veterans Health Administration (VHA) patients and (b) conducting a multisite randomized controlled trial (RCT) with 300 participants to examine the efficacy of this individual CBT intervention in reducing suicidal thoughts and behaviors in VHA patients receiving treatment for a SUD over a 2 year follow-up period.

2. KEYWORDS

Suicide, Suicidal Thoughts, Suicide Attempts, Substance Use Disorders, Alcohol Dependence, Drug Dependence, Addiction, Veterans, OEF/OIF

3. ACCOMPLISHMENTS

- *What are the major goals and objectives of the project?*

The proposed project is a fully-powered randomized controlled trial (RCT) of the CBT intervention versus the SPC intervention for 300 suicidal Veterans seen in SUD Intensive Outpatient treatment at various VHAs to examine changes in suicidal thoughts, non-fatal attempts, substance use and depression for two years post-intervention. The specific aims are to: (1) compare CBT and SPC in reducing the frequency and intensity of suicidal thoughts at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) compare CBT and SPC in decreasing the likelihood of suicide attempts at 1-, 3-, 6-, 12-, 18-, and 24-months. The secondary aims are to (1) compare the CBT condition to the SPC condition in the frequency of illicit drug use, alcohol use, nonmedical opioid medication misuse, self-efficacy and depressive symptoms at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) examine whether OEF/OIF status moderates the effect of treatment assignment (CBT vs. SPC) on post-treatment suicidal thoughts, behaviors and substance use.

As outlined in the SOW, the major goals for the second year of this project are primarily related to conducting the randomized controlled trial and include 1)

recruitment of potential participants for screening and enrollment, 2) conducting baseline assessments, 3) randomization of eligible participants to either intervention condition, 4) delivery of intervention sessions 5) conducting in-person and brief telephone follow-up assessments, 6) providing clinical supervision for study therapists, 7) developing and maintaining study databases, and 8) maintaining regulatory binders.

- *What was accomplished under these goals?*

During this second year, our main objectives, activities, and accomplishments have focused on finalizing study procedures and protocols, training and hiring study staff, receiving final IRB human subject's approval, and beginning study recruitment, enrollment, and intervention delivery. A key objective during this second year was receiving full approval to begin subject recruitment. During the first quarter, we continued to focus on preparing materials for IRB submission and receiving final IRB approvals from several of our study sites. In February of 2015, we received full approval from the Ann Arbor VA IRB and R&D committee. Also in February, we submitted the required Human Research Protocol materials for The University of Michigan and the Ann Arbor VA Medical Center to USAMRMC HRPO for review. In March of 2015, we received full approval from the VA Eastern Colorado Health Care System R&D committee and the Colorado Multiple Institutional Review Board (COMIRB). In April of 2015, we submitted the required Human Research Protocol materials from the Colorado Multiple Institutional Review Board (COMIRB) to USAMRMC HRPO for review. We received our Initial Administrative Review for The University of Michigan, the Ann Arbor VA Medical Center, and the VA Eastern Colorado Health Care System from our Human Subjects Protection Scientists in May, 2015 which required IRB amendments to be submitted to the respective IRB boards to incorporate the required modifications to the protocol. We submitted the amendments to the University of Michigan IRB and Ann Arbor VA IRB in May and received approval in June, 2015. In June, 2015, we also submitted our NIDA Certificate of Confidentiality application to the University of Michigan Institutional Official for signatures and submitted the application to NIDA. We received our Certificate of Confidentiality in November, 2015. We also submitted and received approval for the amendment with HRPO-required changes from the COMIRB in June, 2015. We submitted the approved amendments for final review in late June and received our USAMRMC ORP HRPO approvals for the University of Michigan, the Ann Arbor VA Medical Center, and the VA Eastern Colorado Health System in June, 2015.

In addition, during this second year we also continued to finalize all study procedures, protocols, and databases, including creation of detailed risk management procedures to ensure the safety of participants during their enrollment in the study. We continued the process of hiring additional study staff, including CBT and SPC therapists and Research Assistants at both the Colorado and Michigan study sites. Given the complex, complicated, and serious nature of the population being studied (suicidal Veterans in substance abuse treatment), we continued to spend an increased amount of time training staff members on our risk assessment and management protocols. Study staff participated in extensive training on the nature of suicide and its association with substance use disorders,

as well as participated in role play. In April of 2015, key study staff including Investigators, Project Coordinators, Study therapists, and Consultants met for a project kick-off meeting in Denver, CO. This was a 3-day training which provided an opportunity for all staff to discuss and modify key study protocols and procedures such as risk assessment procedures. Study therapists also participated in intensive clinical training and manual review for the intervention conditions, while the Project Coordinators and research assistants participated in training surrounding measure administration and standard operating procedures. Therapists were able to review materials, discuss the content and suggest revisions, and role play key session scenarios and topics. Based on this meeting, both the CBT and SPC condition manuals were revised. Study therapists contributed to the manual modifications, with guidance from the study's clinical supervisors, and continued to receive intensive training on session delivery through regular supervision calls and mock client role plays of all sessions. The study's clinical supervisors have provided detailed feedback on the role plays to the therapists throughout the training process and continue to provide feedback since recruitment and intervention delivery have begun. We also developed measures of treatment integrity and fidelity for each CBT and SPC therapy session. Key study staff also visited Denver, CO in November of 2015 for an additional meeting to discuss recruitment efforts, intervention delivery, and follow-up procedures to ensure that all study sites are following study protocols and procedures accurately.

Recruitment began at the Ann Arbor VA in July of 2015, at the Denver VA in August 2015, and in Colorado Springs in September of 2015. Through the end of this reporting period, there have been a total of 222 patients who presented for IOP treatment at the study sites. Of those potential participants, we have approached 183 (82.4%) for recruitment and consented 134 (73.2%) participants for the screening portion of the study, of which 125 (93.3%) participants completed the screening questionnaire. Of this final screening sample, 92.8% were male ($n=116$) and the mean age was 48.3 years old. Across all study sites in both Michigan and Colorado, 37 participants (29.6%) who completed the screening questionnaire were eligible to participate in the full study. Of those who were ineligible for participation in the trial, the reasons included: no report of current suicidal ideation (as indicated by a score of five or greater on the Beck Suicidal Ideation Scale [BSS-SR]) (93.2%), having a legal guardian (1.1%), receiving methadone treatment for substance use within the past 6 month (2.3%), experiencing active psychoses (1.1%), and actively participating in other randomized trial at the study site (2.3%). Thirty-four participants (91.9%) were consented and enrolled prior to the end of the reporting period (two participant declined to participate in the full study and one participant was discharged from treatment to another facility before study enrollment could take place). In addition to beginning project recruitment, project staff have established positive relationships with staff at the study sites to ensure successful recruitment of participants during this reporting period including attending staff meetings at the study sites and remaining in communication with treatment staff throughout the recruitment period. These relationships have proved vital in allowing study staff to consistently recruit and enroll participants in the study, and we will continue to maintain these relationships throughout the study. In addition to beginning recruitment, we have started the delivery of Cognitive Behavioral Therapy (CBT) and Supportive Psycho-educational Control (SPC) interventions. To date, we have

15 participants who have been randomized to receive the CBT intervention across sites, and 19 participants have been randomized to receive the SPC intervention. Supervision of the CBT and SPC therapists has been ongoing throughout the reporting period to ensure fidelity of the intervention protocols. Study therapists have continued to monitor participant satisfaction and comprehension of the session content and participants have expressed high levels of satisfaction with the sessions. We have also begun conducting our post-enrollment follow-up assessments. In total through the end of the reporting period, our current study follow-up rate across all time points is 74.1% (70.8% at post-intervention (1-month), 73.7% at 2-month, 75% at 3-month, and 100% at 4-month). At this point, we do not have data to report regarding study aims since recruitment, baseline, and post-intervention follow-up assessments are ongoing.

In addition to the above activities, we continued the process of study coordination and initiation during this quarter. We continued regular project meetings between the Michigan sites (e.g., Ann Arbor, Detroit) and the sites in Colorado (e.g., Colorado Springs and Denver), via phone and/or e-mail and have added regular supervision meetings across sites during this quarter. We continue to discuss issues related to study management including data related issues (e.g. the management and transferring of data, including where and how the data may be stored, creating a shared drive for communication between sites, creating and finalizing study measures, and the creation of the study databases) and risk management issues. We continue to progress towards our study goals, with subject recruitment, enrollment, intervention delivery, and conduction of post-enrollment follow-ups planned to continue through the next year.

- *What opportunities for training and professional development did the project provide?*

Nothing to Report.

- *How were the results disseminated to communities of interest?*

Nothing to Report.

- *What do you plan to do during the next reporting period to accomplish the goals and the objectives?*

During the next reporting period, we plan to continue subject recruitment and enrollment at the study sites, as well as continue intervention delivery and follow-ups with enrolled participants. We are in the process of amending our study protocols with local IRBs in order to expand our recruitment to include all outpatient substance abuse treatment locations at the study sites in addition to the intensive outpatient clinics. We will continue to coordinate with staff at the respective VA SUD IOP clinics and build relationships with additional outpatient clinics in order to identify strategies to accomplish project goals at their treatment clinics. During this reporting period, we were able to identify a site specific PI at the Detroit VA to oversee the project at that location, and during this reporting period we will be working with them to submit our project to their IRB for approval and once approved

begin recruitment at that site. Within the next reporting period we also will hold our first Data Safety and Monitoring Board meeting. Throughout the next reporting period, we will continue to monitor all procedures at each site and ensure that all protocols and procedures are being followed consistently across all study sites. We will also continue with extensive training of all project protocols and procedures with study staff and monitor study staff closely as recruitment, enrollment, intervention delivery, and follow-ups continue to increase in volume to ensure that all study protocols are being accurately followed. Since the population of this study is particularly high risk, all study staff will continue to receive extensive training in managing suicidal and homicidal crises. Project coordinators will work with all study staff in addition to the investigators to monitor risk assessments to ensure all protocols are being followed. We anticipate that this will be an ongoing training, where staff will continue to meet regularly throughout the study to process and refine the management of these issues. We also continue to evaluate our internal study documents during the next reporting period, including project databases and information sheets that will be used to track participants throughout the study. We are optimistic that we will be able to achieve our goals as outlined in our SOW to continue subject recruitment, enrollment, and follow-up within the next reporting period.

4. IMPACT

Nothing to Report.

5. CHANGES/PROBLEMS

- *Changes in approach and reasons for change*

During this reporting period, we received approval from the Science Officer and Grants Officer to expand study recruitment to include VA outpatient substance use disorder treatment at the same study sites. Initially, recruitment of participants focused exclusively on those currently enrolled in the SUD Intensive Outpatient Programs, which require patients to attend SUD treatment programming multiple days per week for several hours per day. While we found recruiting from these SUD IOPs successful in the short-term, we also encountered challenges with the relatively small size of the programs as well as the fact that participants were often so busy and limited by transportation that it was hard for them to make time to participate in research despite their interest in the project. In order to ensure that we will be able to achieve our recruitment goal in the timeframe outlined in our SOW, we feel that expanding the scope of the project to include VA outpatient SUD treatment is essential since outpatient SUD programs at the study sites serve a larger number of patients and provide for greater flexibility in scheduling participants. This modification did not result in any change to our budget or our SOW.

6. PRODUCTS

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

• What individuals have worked on the project?

<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Mark A. Ilgen, PhD</p> <p>Principal Investigator</p> <p>3</p> <p>Dr. Ilgen has reviewed study materials, assisted in the refining and revision of measures and intervention manuals, provided oversight in protocol and study procedures, reviewed regulatory documents, participated in clinical supervision for intervention conditions, aided in hiring and training of new staff, and attended project meetings.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Jennifer Olson-Madden, PhD</p> <p>Site-PI (Denver & Colorado Springs)</p> <p>6</p> <p>Dr. Olson-Madden has facilitated the overall protocol and study coordination of the Denver sites, including the review of study measures, materials, and intervention manuals, overseeing any necessary study-related purchases, co-leading bi-weekly study organization phone meetings, provision of clinical training and supervision, and the preparation and review of regulatory documents.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>James Cranford, PhD</p> <p>Co-Investigator</p> <p>1</p> <p>Dr. Cranford has reviewed study materials, assisted in the revision of project measures, assisted with data management issues and data analysis, and attended project meetings.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Stephen Chermack, Ph.D.</p> <p>Co-Investigator</p> <p>1</p> <p>Dr. Chermack has reviewed study materials, assisted in the revision of our intervention manuals, and provided training and clinical supervision to study therapists in both conditions.</p>

<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Amanda Price, MS</p> <p>Project Manager</p> <p>9</p> <p>Ms. Price has facilitated the overall protocol and study coordination of the study sites, including management and coordination of participant recruitment, enrollment, intervention delivery, and follow-up assessments, participation in subject recruitment and consenting, conducting enrollment interviews, randomization of eligible participants, facilitation of intervention delivery, and conducting follow-up assessments, attended and participated in project meetings, including coordinating monthly Investigator meetings, containing in the training and management of study staff members, has assisted in the creation of study databases and project binders, and has assisted in modifying study materials including study measures, intervention manuals, risk management protocol, and general project procedure protocols.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Linda Mobley, MS</p> <p>IRB Coordinator</p> <p>7</p> <p>Mrs. Mobley assisted in revising the protocols and study materials, attended project meetings, completed paperwork for local IRB submissions and project submissions to USAMRMC HRPO, and completing documents for the Certificate of Confidentiality application.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Ariel Friese, MS, LPC</p> <p>Project Coordinator (Denver & Colorado Springs)</p> <p>9</p> <p>Ms. Friese has worked on preparation, review and submission of regulatory documents, participation in weekly study organization phone meetings, coordinated communication with project partners, recruitment, screening, enrollment and follow-up of participants, and budget management.</p>

<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Amanda Regalia, LMFT</p> <p>Study Therapist – CBT condition (Denver & Colorado Springs)</p> <p>9</p> <p>Ms. Regalia has participated in weekly clinical supervision and training for the CBT treatment condition. She has been providing therapy sessions to participants enrolled in the CBT condition and managing all aspects of treatment, risk management in sessions and follow-up.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Erin Goldman, LMSW</p> <p>Study Therapist- CBT condition (Ann Arbor & Detroit)</p> <p>7</p> <p>Mrs. Goldman has assisted in reviewing and editing the CBT therapist manual, participated in ongoing clinical supervision and training in the delivery of the CBT intervention, attended project meetings and trainings, and helped prepare study-related materials for participants.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Jennifer Powers, LCSW</p> <p>Study Therapist – SPC condition (Denver & Colorado Springs)</p> <p>8</p> <p>Ms. Powers has participated in weekly clinical supervision and training for the SPC treatment condition. She has been providing therapy sessions to participants enrolled in the SPC condition and managing all aspects of treatment, risk management in sessions and follow-up.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Michelle Sanborn, MA</p> <p>Study Therapist – SPC condition (Ann Arbor & Detroit)</p> <p>7</p> <p>Mrs. Sanborn has assisted in reviewing and editing the SPC therapist manual, participated in ongoing clinical supervision and training in the delivery of the SPC intervention, attended project meetings and trainings, and helped prepare study-related materials for participants.</p>
<p>Name:</p> <p>Project Role:</p> <p>Researcher Identifier (e.g. ORCID ID):</p> <p>Nearest person month worked:</p> <p>Contribution to the project:</p>	<p>Jing Wang, MS</p> <p>Data Manager (previous)</p> <p>2</p> <p>Ms. Wang reviewed study measures and continues to develop systems for project databases and electronic data and storage. Please note, Ms. Wang left the position in September, 2015.</p>

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Kristen Enriquez, MA Research Assistant (Denver & Colorado Springs) 7 Ms. Enriquez has assisted in all aspects of data management, as well as participant recruitment, screening, tracking and enrollment, including the provision of screening measures, baseline interviews and measures and follow-up interviews and measures.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Katrina Hernandez, BA Research Assistant (Ann Arbor & Detroit) 3 Mrs. Hernandez has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, participated in intervention role play sessions as a mock client, and participated in participant recruitment, consenting, enrollment, and follow-up.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Oluchi Uju-Eke, MPH Research Assistant (Ann Arbor & Detroit) 3 Ms. Uju-Eke has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, participated in the creation of study databases, participated in intervention role play sessions as a mock client, and participated in participant recruitment, consenting, enrollment, and follow-up.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Kathleen Paige Temporary Student Research Assistant (Ann Arbor & Detroit) 1 Ms. Paige has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, and participated in intervention role play sessions as a mock client. Please note, Ms. Paige left the position in August, 2015.

- *Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?*

YES, please see Other Support pages attached.

- *What other organizations were involved as partners?*

Organization Name: Denver Research Institute

Location of Organization: Denver, CO

Partner's contribution to the project (identify one or more):

- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);

8. SPECIAL REPORTING REQUIREMENTS

Please find an updated version of the QUAD CHART in the appendices.

9. APPENDICES

- a. Other Support
- b. Quad Chart

Changes in Other Support for Dr. Ilgen:

1. Effort ended on VA HSR&D IIR 09-333-2 (PI – Chermack)
2. Effort ended on VA QUERI (PI – Ilgen)
3. Effort ended on VA HSR&D CRE-010 (PI – Timko)
4. Effort started on VA HSR&D IIR 13-322-2 (PI – Bohnert)
5. Effort started on VA HSR&D IIR 14-103-2 (PI – Ilgen)

OTHER SUPPORT**ILGEN, MARK**

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE**University Of Michigan Projects:**

(Ilgen, M.)	04/01/11 – 03/31/16	0.96 calendar
NIH/NIDA R01 DA029587	\$217,344	
Psychosocial Pain Management during Addictions Treatment to Improve Outcomes		

This randomized control trial is designed to determine the efficacy of a group based cognitive-behavioral pain management intervention in comparison to a Supportive Psychoeducation Control (SPC) group in individuals with co-occurring pain and substance use disorders recruited at the start of residential treatment program.

(Ilgen, M.)	05/01/13 – 02/28/17	3.36 calendar
NIH/NIDA R01 DA033397	\$369,576	
Medical Marijuana: Longitudinal Trajectories in Use, Pain and Functioning		

With the ongoing policy debate and the growing popularity of medical marijuana programs in the United States, it is essential to understand the ramifications of medical marijuana use for individuals who seek access to it. The proposed study will identify a cohort of 800 individuals who are seeking to obtain medical marijuana and examine their substance use (marijuana and other drug use), pain (pain level and behavioral pain tolerance), HIV risk profile, functioning (mental, physical, employment, and legal functioning), and health service use over the course of two years. The resulting data will inform the debate surrounding medical marijuana use and could help shape strategies to identify and intervene with individuals at risk for problems related to substance use.

(Ilgen, M.)	12/30/13 – 12/29/18	3.16 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,244,432	(1.2 calendar
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		cost shared with the VA)

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

Veterans Health Administration Projects:

(Bohnert, A.)	07/01/15 - 06/30/19	1.6 calendar
VA Health Administration–HSR&D, IIR 13-322-2	\$324,372	
Primary Care Intervention to Reduce Prescription Opioid Overdoses: Prescription Opioid Safety Trial (POST)		

This project aims to determine the safety of high-dose opioid use among Veterans presenting to primary care and mental health clinics, it is of critical importance to involve researchers who have expertise in overdose risk, opioid use, primary care and mental health care settings, pharmacoepidemiology, and longitudinal data analysis, as well as sufficient support staff.

(Ilgen, M.)	07/01/15 - 06/30/19	2.4 calendar
VA Health Administration–HSR&D, IIR 14-103-2	\$236,501	
Facilitating use of the Veterans Crisis Line in High-Risk Patients		

This study will be a randomized controlled trial of the impact of a new brief intervention, called Crisis Line Facilitation, compared to enhanced usual care on utilization of the Veterans Crisis Line and other mental health services use as well as on suicide attempt(s) in participants who are currently treated for a suicidal crisis in a VHA inpatient psychiatric unit.

OVERLAP

None

Changes in Other Support for Dr. Blow:

1. Effort started on VA HSR&D IIR 13-322-2 (PI – Bohnert)
2. Effort started on VA HSR&D IIR 14-103-2 (PI – Ilgen)

OTHER SUPPORT

BLOW, FREDERIC C

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

University Of Michigan Projects:

(Blow, F.)	07/20/10 – 06/30/16	0.48 calendar
NIH/NIAAA R01 AA018659	\$414,966	
Optimizing Alcohol Brief Interventions in the ED: Computer vs. Clinician Delivery		

The proposed study will use computerized screening via touch-screen computer tablets with audio to recruit 750 inner-city ED patients screening positive for at-risk or problem alcohol use. The aims of the study are to develop and refine tailored motivational brief interventions that are parallel in structure but have varied delivery modalities (computer vs. therapist) for patients with at-risk or problematic alcohol use, and to conduct a randomized controlled trial comparing the efficacy of these BI approaches (C-BI, T-BI, control) on subsequent alcohol consumption and alcohol consequences, including alcohol-related injury, mental and physical-health functioning, and HIV risk behaviors at 3-, 6-, and 12-months post-ED visit.

(Blow, F.)	09/20/13 – 08/31/18	1.9 calendar
NIH / NIAAA / DoD R01 AA023122	\$417,751	(1.2 calendar
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI		cost shared with the VA)

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

(Ilgen, M.)	12/30/13 – 12/29/18	0.12 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,244,432	
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(Blow, F.)	09/01/14 – 08/31/19	3.0 calendar
Case Western Reserve University / DoD/USAMRMC–	\$236,570	
W81XWH-14-2-0007		
Early Intervention to Reduce Alcohol Misuse and Abuse In the Ohio Army National Guard		

The proposed project is a fully-powered randomized controlled trial of a Web- and text-based alcohol brief intervention (WT-BI) versus and Enhanced Usual Care (EUC) condition for Ohio National Guard members who meet criteria for unhealthy drinking in the previous three months.

Veterans Health Administration Projects:

(Chermack, S.)	09/01/11 – 02/28/16	0.24 calendar
VA Health Services Research and Development	\$230,107	
(HSR&D) Application IIR 09-333-2		
Impact of Interventions to Reduce Violence and Substance Abuse among VA Patients		

The primary objectives of this study are to examine the impact on both substance use and violence outcomes of: a) an acute treatment phase integrated Motivational Interviewing-Cognitive Behavioral Treatment intervention (MI-CBT); and b) MI-CBT plus a violence and substance use prevention Continuing Care intervention (MI-CBT+CC) intervention. The results will enhance the development and implementation of effective violence prevention interventions to be incorporated into VA SUD treatment settings which will have a significant impact on the lives of Veterans and their families.

(Bohnert, A.)	07/01/15 - 06/30/19	0.6 calendar
VA Health Administration–HSR&D, IIR 13-322-2	\$324,372	
Primary care Intervention to Reduce Prescription Opioid Overdoses: Prescription Opioid Safety Trial (POST)		

This project aims to determine the safety of high-dose opioid use among Veterans presenting to primary care and mental health clinics, it is of critical importance to involve researchers who have expertise in overdose risk, opioid use, primary care and mental health care settings, pharmacoepidemiology, and longitudinal data analysis, as well as sufficient support staff.

(Kales, H.)	01/01/13 - 07/30/16	0.6 calendar
VA Health Administration–HSR&D, IIR 12-144-2	\$252,634	
Morbidity and Mortality Risks with Antipsychotic use in Parkinson's Disease		

This study will use Veterans Affairs' national databases to examine the outcomes of AP use in large groups of PDP patients, supplementing the data with important clinical information extracted from electronic medical records using an electronic medical record search engine. Specifically, the 6- and 12-month rates and causes of death and complications (hospitalizations, emergency room visits) will be compared for two comparable groups of PDP patients, one prescribed an AP and the other not treated with an AP.

OVERLAP

None

Changes in Other Support for Dr. Bohnert:

1. Effort ended on NIH/NIAAA R01 AA018659 (PI – Blow)
2. Effort ended on VA HSR&D CDA 09-204 (PI – Bohnert)
3. Effort started on VA HSR&D IIR 13-322-2 (PI – Bohnert)
4. Effort started on VA HSR&D IIR 14-103-2 (PI – Ilgen)

OTHER SUPPORT**BOHNERT, AMY**

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE**University of Michigan Projects:**

(Bohnert, A.)	03/01/14 – 02/28/17	2.4 calendar
NIH/NIDA R34 DA035331	\$191,090	
Developing a prescription opioid overdose prevention intervention		

This behavioral intervention development project aims to expand and refine a three session intervention to prevention prescription opioid overdoses among individuals in residential addictions treatment and to conduct a pilot randomized controlled trial of the intervention compared to an equal attention control condition.

(Ilgen, M.)	04/01/11 – 03/31/16	0.24 calendar
NIH/NIDA R01 DA029587	\$217,344	
Psychosocial Pain Management During Addictions Treatment to Improve Outcomes		

This randomized control trial is designed to determine the efficacy of a group based cognitive-behavioral pain management intervention in comparison to a Supportive Psychoeducation Control (SPC) group in individuals with co-occurring pain and substance use disorders recruited at the start of residential treatment program.

(Ilgen, M.)	12/30/13 – 12/29/18	1.03 calendar
DoD/USAMRMC – W81XWH-14-1-0005	\$1,244,432	
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(Blow, F.)	09/20/13 – 08/31/18	0.48 calendar
NIH / NIAAA / DoD R01 AA023122	\$417,751	
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI		

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

(Bohnert, A.)	09/01/14 – 08/31/16	1.8 calendar
Center for Disease Control and Prevention - IPA	\$23,406	
14IPA1405517		

The assignment will allow CDC to gather crucial information to address the following key areas of the Prescription Drug Overdose team's strategic direction: 1) Effective monitoring and surveillance of opioid prescribing and associated health outcomes. 2) Analyses to determine key drivers of opioid pain reliever overdose and effective strategies to prevent opioid pain reliever overdose. In addition, the assignment will allow CDC and University of Michigan researchers to examine the relationship between opioid prescriptions and clinical outcomes in order to inform opioid prescribing guidelines as well as recommendations for coordinated care for patients with pain.

Veterans Health Administration Projects:

(Bohnert, A.)	07/01/15 - 06/30/19	3.0 calendar
VA Health Administration–HSR&D, IIR 13-322-2	\$324,372	
Primary Care Intervention to Reduce Prescription Opioid Overdoses: Prescription Opioid Safety Trial (POST)		

This project aims to determine the safety of high-dose opioid use among Veterans presenting to primary care and mental health clinics, it is of critical importance to involve researchers who have expertise in overdose risk, opioid use, primary care and mental health care settings, pharmacoepidemiology, and longitudinal data analysis, as well as sufficient support staff.

(Ilgen, M.)	07/01/15 - 06/30/19	1.8 calendar
VA Health Administration–HSR&D, IIR 14-103-2	\$236,501	
Facilitating use of the Veterans Crisis Line in High-Risk Patients		

This study will be a randomized controlled trial of the impact of a new brief intervention, called Crisis Line Facilitation, compared to enhanced usual care on utilization of the Veterans Crisis Line and other mental health services use as well as on suicide attempt(s) in participants who are currently treated for a suicidal crisis in a VHA inpatient psychiatric unit.

OVERLAP

None

Changes in Other Support for Dr. Chermack:

1. Effort ended on NIH/NIAAA R01 AA018659 (PI – Blow)
2. Effort ended on Henry M. Jackson Foundation/DoD BAA-10-1 (PI – King)

OTHER SUPPORT**CHERMACK, STEPHEN**

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE**University of Michigan Projects:**

(Ilgen, M.)	04/01/11 – 03/31/16	0.18 calendar
NIH/NIDA R01 DA029587	\$217,344	
Psychosocial pain management during addictions treatment to improve outcomes		

The proposed project will determine the efficacy of a cognitive-behavioral pain management intervention targeting individuals with co-occurring pain and substance use disorders who will be recruited at the start of a residential treatment episode. This proposed efficacy study will provide crucial data on a brief, innovative method designed to improve outcomes in the large numbers of individuals with both substance use disorders and chronic pain.

(Ilgen, M.)	12/30/13 – 12/29/18	1.28 calendar
DoD/USAMRMC W81XWH-14-1-0005	\$1,244,432	
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders		

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

(King, C.)	08/11/14 – 07/31/19	0.96 calendar
NIH/NIMH R01 MH103244	\$437,200	
Electronic Bridge to Mental Health (eBridge) for College Students		

We propose to conduct a large-scale randomized controlled intervention trial across multiple universities to determine the impact of eBridge on college students' readiness to seek mental health treatment, linkage to mental health treatment, and mental health outcomes. We will also determine the extent to which the online counseling mediates intervention effectiveness.

Veterans Health Administration Projects:

(Chermack, S.)	04/01/11 – 03/31/16	1.8 calendar
VA Health Services Research and Development (HSR&D) Application IIR 09-333-2	\$230,107	

Impact of Interventions to Reduce Violence and Substance Abuse among VA Patients

The primary objectives of this study are to examine the impact on both substance use and violence outcomes of: a) an acute treatment phase integrated Motivational Interviewing-Cognitive Behavioral Treatment intervention (MI-CBT); and b) MI-CBT plus a violence and substance use prevention Continuing Care intervention (MI-CBT+CC) intervention. The results will enhance the development and implementation of effective violence prevention interventions to be incorporated into VA SUD treatment settings which will have a significant impact on the lives of Veterans and their families.

OVERLAP

None

Changes in Other Support for Dr. Valenstein:

1. Effort ended on VA HSR&D IIR-10-176-3 (PI – Zivin)
2. Effort ended on VA HSR&D IIR 10-340-3 (PI – Kilbourne)
3. Effort ended on VA QUERI RRP 12-511 (PI – Zivin)
4. Effort ended on VA QUERI RRP 12-505 (PI – Pfeiffer)
5. Effort started on State of Michigan – Child Collaborative Care Model (PI – Marcus)
6. Effort started on VA HSR&D IIR 14-345 (PI – Pfeiffer)
7. Effort started on VA HSR&D IIR 14-324 (PI – Zivin)

OTHER SUPPORT

VALENSTEIN, MARCIA

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

UNIVERSITY OF MICHIGAN

1R01AA023122-01 (Blow)

National Institute on Alcohol Abuse and Alcoholism (NIAAA) 09/20/13-08/31/18 1.80 Calendar
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI \$417,751

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

BCBSM Foundation 10/15/2013-06/15/2015 (NCTX3/15/16) 0.72 Calendar
Assessing Tailored Mental Health Management Support for Primary Care \$94,814

The goal of this project is assess the feasibility and effectiveness of a tailored mental health care management (TaMMs) intervention for patients in safety-net primary care clinics. This intervention is designed to support the care of large numbers of patients, increasing or decreasing the intensity of support services, to deliver "just enough" and "just in time" support of their mental health treatment.

Log 11224006 (Ilgen)

DoD/USAMRMC W81XWH-14-1-0005 12/30/13 – 12/29/18 0.60 Calendar
Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders \$1,244,432

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

R34MH103447(Pfeiffer) 07/15/2014 - 05/31/2017 0.60 Calendar
NIMH R34 \$200,000
Peer mentorship to reduce suicide risk following psychiatric hospitalization

Risk of suicide is significantly elevated during the period of time immediately following inpatient psychiatric treatment. This study will develop and pilot test a peer mentorship intervention to reduce the risk of suicide among patients psychiatrically hospitalized at the University of Michigan.

State of Michigan Community Health HHS (Dalack)	10/1/2015-9/30/2016	0.54 Calendar
Project 9		\$164,955
Tailored Mental Health Management Support for Primary Care		

This project provides a continuum of monitoring and intervention services, tailored to the needs of patients with depression and anxiety, with the most intensive services being targeted to the highest-risk patients.

R01-MH-096699 (Aikens/Piette)	9/18/12-6/30/17	1.20 Calendar
National Institute of Mental Health		\$499,958
<i>Telemonitoring Enhanced Support for Depression Self-Management.</i>		

This is an RCT to compare the effectiveness of telemonitoring support with care partners to usual care on depression severity outcomes among low-income primary care patients.

W81XWH-11-PHTBI-BAPHA (Kees)	09/30/2012-09/29/2016	0.11 Calendar
Dept. of Defense/MSU (RC102123A)		\$27,862 subcontract
<i>Risk, Resiliency, and Coping in National Guard Families</i>		

Examine risk and resilience in National Guard military families across the longitudinal course of a deployment cycle, with up to three years follow-up.

Bristol-Myer Squibb Foundation (Valenstein transferred to Kees 2/14)	11/01/12 – 11/30/16	0.24 Cal
<i>Implementing Peer Advisors for Veteran Education (PAVE)</i>		\$300,126

This grant will support the implementation and evaluation of the Peer Advisors for Veteran Education (PAVE), a peer-to-peer program that connects student Veterans on participating campuses with upper class student Veterans (Peer Advisors) who can help identify emerging mental health issues and assist Veteran students in navigating college life and accessing appropriate mental health services and other supportive resources.

State of Michigan Department of Community Health (Marcus)	10/1/15 – 9/30/16	0.60 Cal mths
Enhancement of the Michigan Child Collaborative Care Model: Expanding Access and Monitoring Outcomes		\$243,252

This project aims to develop an innovative care model to increase access to mental health treatment for underserved children and adolescents in Michigan to include ongoing follow up of patients, and the establishment of metrics that provide data on uptake of the program (utilization, changes in prescribing, provider and patient satisfaction, treatment recommendation follow through and adherence, changes in primary care provider confidence and competence), and changes in clinical outcomes, including symptom severity data.

DEPARTMENT OF VETERANS AFFAIRS

IIR 12-109 (Pfeiffer)	1/1/2013-12/30-2016	1.09 Calendar
Department of Veterans Affairs, Health Services Research and Development		\$192,766
<i>Veteran College Students Mental Health and Academic Achievement.</i>		

This project aims will be to 1) Assess cross-sectional and longitudinal prevalence of mental health symptoms, hazardous alcohol use, and levels of wellbeing among a *representative* sample of Veteran and comparison students. 2) Assess Veteran students' use of VA and non-VA mental health services (including college mental health services), treatment preferences, and perceived treatment barriers, and 3) Assess cross-sectional and longitudinal *associations* between Veteran students' mental health symptoms, treatment, and academic performance.

IIR13-310 10/1/14-3/31/18 0.6 Calendar
Department of Veterans Affairs, Health Services Research and Development \$347,455
Veteran Peer-Assisted Computerized Cognitive Behavioral Therapy for Depression

The purpose of this study is to conduct a Hybrid Type I RCT of Peer-Supported cCBT (PS-cCBT) versus enhanced usual care (EUC) for 330 patients with new episodes of depression diagnosed in primary care at three VA sites and their CBOCs. Our Primary Specific Aims are to 1) compare PS-cCBT versus EUC on symptomatic, functional and recovery-oriented outcomes, and 2) compare PS-cCBT versus EUC on acquisition of depression coping skills, initiation and continuation of antidepressant medication, and initiation and completion of more intensive traditional psychotherapy (contingent on symptom level).

IIR 14-345 Pfeiffer (PI) 01/01/2016 - 12/31/2019 1.20 Calendar Months
HSR&D, Department of Veterans Affairs Total Direct Costs: \$1,095,323
Incorporating Treatment Outcomes into Quality Measurement of Depression Care

The purpose of this project is to develop and assess outcome quality measures for depression and assess the relationships between outcomes and care processes, including a new measure of treatment intensification, and to determine the association between facility characteristics and depression care processes and outcomes.

IIR 14-324 Zivin (PI) 01/01/2016 - 6/30/2019 1.20 Calendar Months
HSR&D, Department of Veterans Affairs Total Direct Costs: \$1,071,818
VA responses to guidance regarding risks of psychotropic medication use

The goal of this study is to examine multilevel responses to external warnings regarding psychotropic medications, specifically variation in the adoption of warnings by VISNs, VA facilities, and providers, and the effect of varying levels of pharmacy integration on response to warnings. The specific aims include 1) to assess and describe PBM and VISN-level responsiveness and variation in responsiveness to warnings regarding psychotropic medications, 2) to assess prescribing patterns before and after warnings regarding psychotropic medications, and 3) To understand specific strategies used by facilities and providers with high response to warnings and barriers encountered by facilities and providers with low response to warnings.

OVERLAP

None

Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

Log Number: 11224006 and EDMF 5787

W81XWH 14-1-0005



PI: Mark Ilgen, PhD

Org: University of Michigan

Award Amount: \$6,783,574

Study/Product Aim(s)

Primary Aims:

- Compare CBT and SPC in reducing the frequency and intensity of suicidal thoughts at during the multiple follow-up periods.
- Compare CBT and SPC in decreasing the likelihood of suicide attempts at multiple follow-up periods

Approach

The proposed project is a fully-powered multi-site randomized controlled trial of the CBT intervention versus the SPC condition for suicidal Veterans seen in Veterans Health Administration (VHA) outpatient SUD treatment programs. Participants will be followed up once a month for the first six months (i.e., 1-month, 2,-month) and then every six months (i.e., 12-months, 18 months, 24-months) thereafter.



Caption: Helping Veterans with Substance Use Disorders (image taken from "Google Images-Images for Reuse")

Accomplishments: Received all regulatory approvals, began project recruitment in both Michigan and Colorado sites, began participant enrollment and randomization into the randomized controlled trial, began intervention delivery and post-treatment follow-up assessments , continued project trainings for study therapists and research assistants.

Timeline and Cost

Activities	CY14	CY15	CY16	CY17	CY18
Project Start up					
Project Recruitment					
Follow-up Assessments					
Data Management & Analysis					
Project Reports & Dissemination					
Estimated Budget	\$1,232,338	\$1,631,991	\$1,602,345	\$1,377,263	\$939,637

Goals/Milestones

CY14-CY15 (January 2015): Project Start up

- ☒ Hire and train study staff
- ☒ Assemble data safety and monitoring board
- ☒ Obtain Certificate of Confidentiality
- ☒ Obtain Human Subjects and Research & Development Approval
- ☒ Modify study procedures and measures
- ☒ Refine risk management procedures and intervention

CY16-CY 18 (January 2018) Goals: Conducting the RCT

- ☐ Recruit, consent, and screen participants (*in progress*)
- ☐ Conduct baseline and follow-up interviews (*in progress*)
- ☐ Conduct therapy sessions (*in progress*)
- ☐ Conduct Data Safety and Monitoring Board meetings

CY 18 (October 2018) Goals: Project Management

- ☒ Create and maintain participant tracking databases
- ☐ Conduct analyses and quality checks
- ☒ Submit regular progress reports

Budget Expenditure to Date

Projected Expenditure: \$2,864,329

Actual Expenditure: \$1,033,985

Updated: (Ann Arbor (MI), January 27, 2016)